

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation the successful rate of Wheat Oral Immunotherapy to induce wheat tolerance in wheat allergic patients

Protocol summary

Summary

This is an interventional study investigating the efficacy, safety and immunological mechanisms of oral wheat desensitization therapy in wheat allergic children. Wheat allergic children who meet the inclusion criteria, are recruited to the study. Patients having uncontrolled asthma, other lung disease, cardiovascular disease or other significant systemic disease and patients having poor compliance are excluded. Anaphylaxis is confirmed by DBPCFC in all patients. At first all patients take Loratadine and Montelukast, to prevent the severe adverse reaction, three days prior to admission. then OFCs (oral food challenges) is performed to determine the initial dose of OIT. In build up phase, patients take cake. if they can take it without severe reactions, they were asked to take bread A, which contains 5.28 gr gluten in 100gr (start from 15 , increase up to 30gr). the amount of bread increase twice a week . in third step they start from 20 gr of bread B, which contains 8.8 gr gluten in 100g. After finishing build up phase, they were asked to take 60g of bread in a day (maintenance phase). If they can keep taking wheat products without adverse reactions for 3 months, they will aske to eliminate wheat for 2 weeks, then they receive OFCs. If this challenges were negative, we regarde them as tolerant. If positive, we regarde them as desensitization conditions. In addition to clinical measures, some immunological mechanisms of desensitization (Skin prick test, Wheat sIgE, and total IgE) is measured at the first day, at the end of build up phase, and Maintenance phase.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081214305N2**

Registration date: **2015-04-04, 1394/01/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-04, 1394/01/15

Registrant information

Name

Delara Babaie

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

dbabaie@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Pediatric Infections Research Center of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the successful rate of Wheat Oral Immunotherapy to induce wheat tolerance in wheat allergic patients

Public title

Oral immunotherapy in patient with wheat anaphylaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria 1. Wheat allergic children aged over 2 years with history of severe symptoms and positive SPT 2. Elevated serum wheat specific IgE 3. Immediate reaction in open oral wheat challenge test Exclusion Criteria: • Uncontrolled asthma • Other chronic lung or renal disease • Cardiovascular disease or other significant systemic disease • Patients having poor compliance

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Shahid Aarabi street, Yaman street, Shahid Chamran
highway

City

Tehran

Postal code

Approval date

2014-12-15, 1393/09/24

Ethics committee reference number

13554-87-1-1393

Health conditions studied

1

Description of health condition studied

Wheath anaphylaxia

ICD-10 code

T78.0

ICD-10 code description

Anaphylactic shock due to adverse food reaction

Primary outcomes

1

Description

Level of total IgE in plasma

Timepoint

Start of oral immunothrapy,at the end of oral immunothrapy,after maintenace phase

Method of measurement

Measure of plasma level

2

Description

Level of specific IgE for wheat in plasma

Timepoint

Start of oral immunothrapy,at the end of oral immunothrapy,after maintenace phase

Method of measurement

Measure of plasma level

3

Description

Size of wheal and flare of wheat skin test

Timepoint

Start of oral immunotherapy,After maintenace phase

Method of measurement

Measure of size according millimeter

Secondary outcomes

empty

Intervention groups

1

Description

OFCs (oral food challenges) is performed to determine the initial dose of OIT. In build up phase, patients take cake. if they can take it without severe reactions, they were asked to take bread A, which contains 5.28 gr gluten in 100gr (start from 15 , increase up to 30gr). the amount of bread increase twice a week . in third step they start from 20 gr of bread B, which contains 8.8 gr gluten in 100g.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children' s Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pediatric Infections Research Center of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Delara babaie
Street address
Mofid Children's Hospital, Shariati street
City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pediatric Infections Research Center of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mitra sahragard
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty